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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 11/07/2002
C(2002) 2733

NOT FOR PUBLICATION

**COMMISSION DECISION**

**of [.....]**

**amending Decision C(2001)818 on the marketing authorization for the medicinal product for human use**

**"TARGRETIN - bexarotene"**

**(Text with EEA relevance)**

ONLY THE ENGLISH TEXT IS AUTHENTIC.

**COMMISSION DECISION**

**of 11/07/2002**

**amending Decision C(2001)818 on the marketing authorization for the medicinal product for human use**

**"TARGRETIN - bexarotene"**

**(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], as amended by Commission Regulation (EC) No 649/98[2],

Having regard to Commission Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93[3], as amended by Commission Regulation (EC) No 1069/98[4], and in particular Article 5(2) thereof,

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products,

Whereas:

(1) The medicinal product "TARGRETIN - bexarotene" entered in the Community register of medicinal products under No EU/1/01/178/001 authorised by Commission Decision C(2001)818 of 29 March 2001, as amended, complies with the requirements set out in Regulation (EEC) No 2309/93.

(2) Ligand Pharmaceuticals UK Ltd submitted an application on 28 May 2002 pursuant to Article 4(1) set out in Regulation (EC) No 542/95.

(3) The European Agency for the Evaluation of Medicinal Products delivered a favourable opinion formulated on 11 June 2002 by the Committee for Proprietary Medicinal Products,

(4) Decision C(2001)818 should therefore be amended accordingly.

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[1] OJ No L 214, 24. 8. 1993, p. 1.
[2] OJ L 88, 24.3.1998, p. 7.
[3] OJ No L 55, 11.3.1995, p. 15
[4] OJ L 153, 27.5.1998, p. 11

(5) In accordance with Article 5(2) of Regulation (EC) No 542/95, this Decision shall take effect retroactively on the 31st day following receipt by the European Agency for the Evaluation of Medicinal Products of the application relating to it.

HAS ADOPTED THIS DECISION:

*Article 1*

Decision C(2001)818 is amended as follows:

1. Annex I is replaced by Annex I to this Decision;

2. Annex III (A and B) is replaced by Annex II to this Decision.

*Article 2*

This Decision shall apply from 27 June 2002.

*Article 3*

This Decision is addressed to Ligand Pharmaceuticals UK Ltd, Innovis House, 108 High Street, Crawley, West Sussex RH10 1BB, UNITED KINGDOM.

Done at Brussels, 11/07/2002

*For the Commission*
*Erkki LIIKANEN*
*Member of the Commission*